IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Terri L. Butler et al.	Examiner:	Traviss C. McIntosh, III
Serial Number:	10/692,338	Group art unit:	1623
Filed:	23 October 2003	Docket:	BP.012US2
Title:	COMPOSITIONS AND METHODS FOR IMPROVING CARDIOVASCULAR FUNCTION		

SUPPLEMENTAL INFORMATION

Before examining this Continuation Application, please consider this information. At the time this application was filed on October 23, 2003, the parent Application, SN 09/917,292, was under final rejection. Among the rejections, former Examiner La Tonia M. Fisher rejected claims 1-3 and 9 and 16 under 35 USC 103 (a) as obvious from the references of record (Foker, Cotter and Wakat)..

Beginning in October 1, 2002, Bioenergy, the assignee of this application, through its wholly owned subsidiary, Valens Labs, began marketing the product for cardiac rehabilitation under its registered trademark, CORvalen. Figure 1 illustrates the commercial success achieved. Note that the calendar year 2002 represents only the final quarter of 2002. Each point represents the total dollar sales for that calendar year. The dotted curve leading to CY 2005 is an *underestimate* of expected sales, which is calculated for purposes of this graph simply as 12/5 of the sales to June 1, 2005. Based on the rate of increase of sales, actual sales are expected to reach or exceed one million dollars in this calendar year.

Figure 2 shows a snapshot of FY 2005 sales in units sold for the first two quarters of FY 2005. The three CORvalen products are: #0211 = 70 grams of D-ribose; #0212 = 280 grams D-ribose; #0333 = 340 grams D-ribose with malate. The top bar graph shows direct sales by Valens Labs. These sales are generally a follow-up to physician-recommended CORvalen. The second bar graph shows sales through cardiac rehabilitation clinics.

At this time, June of 2005, CORvalen has been taken for more than a year by thousands of patients, reinforcing the early studies that showed that low doses that avoided the severe gastrointestinal distress shown, for example, by the 15 gram doses of Dr. Pliml (summarized on page 12, lines 23-30 of the specification) are efficacious in improving the status of patients needing cardiac rehabilitation. Examiner Fisher's 35 U.S.C.§ 103 (a) rejections were based on the references of record Foker, Cotter and Wakat. As explained in the affidavit of Dr. John A. St. Cyr, an inventor of the present invention, Foker was the first to research the effect of ribose on an ischemic heart in an intact animal. Dr. Pliml carried out several studies following the teachings of Foker, who used 17 grams of ribose delivered intravenously to a 25-30 kg dog. Recognizing the greater weight of a human subject and also that oral administration does not have the bioavailability of intravenous administration, Dr. Pliml, in his studies, used 15 to 20 gram doses. His studies were generally carried out for only three days, probably as long a term as his patients were able to tolerate the side effects of high doses of ribose.

The present inventors have now shown that low doses of ribose are efficacious for cardiac rehabilitation and that chronic administration of low doses can be tolerated

If Examiner McIntosh would find additional information helpful in determining the patentability of the pending claims, I would be pleased to present a formal affidavit.

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